Pollogen™

510(K) SUMMARY

Applicator 3 Fractional (A3F)

510(k) Number K122200

APR 18 2013

Applicant's Name: Pollogen Ltd.
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Tel Aviv
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Contact Person: Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Applicator 3 Fractional (A3F)***

Summary Preparation Date: July 18, 2012

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

Pollogen's ***Applicator 3 Fractional (A3F)*** is a treatment handpiece to be attached to the FDA cleared Pollogen's apollo™ system (K111026).

The A3F tip emits bipolar RF energy that flows between electrodes to create micro-ablation points on the skin, forming superficial ablation with a volumetric non ablative heating effect in the dermis.

Intended Use Statement:

The ***Applicator 3 Fractional (A3F)*** is intended for dermatological procedures requiring ablation and resurfacing of the skin

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
Syneron Matrix RF Applicator	**K073572**	Sep 17, 2008

Performance Standards:

Applicator 3 Fractional (A3F) complies with

- ***IEC 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

- ***IEC 60601-2-2*** - Medical Electrical Equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment.

A detailed description appears in **Section 14**.

Summary of Pre-Clinical performance data:

The safety and efficacy of the ***Applicator 3 Fractional (A3F)*** was supported by performing histological evaluation study on porcine skin.

The results of this study clearly indicate that the ***Applicator 3 Fractional (A3F)*** offers an effective, safe device for skin resurfacing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Pollogen, Ltd.
% QSite
Mr. Yoram Levy
31 Haavoda Street
Binyamina 30500 Israel

Re: K122200
Trade/Device Name: Applicator 3 Fractional (A3F)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 20, 2013
Received: February 26, 2013

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pollogen™

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k122200

Device Name: ***Applicator 3 Fractional (A3F)***

Indications for Use: The ***Applicator 3 Fractional (A3F)*** is intended for dermatological procedures requiring ablation and resurfacing of the skin

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Joshua C. Nipper For

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number: K122200